CE 0051

# INSTRUCTION MANUAL
# ALSATOM SU 50-MPC, SU 100-MPC, SU 140-MPC, SU 140/D-MPC

This unit is manufactured by ALSA APPARECCHI MEDICALI S.R.L., Via C. Bonazzi 16, 40013 Castel Maggiore (BO), Italy, that guarantees its safety, reliability and performances only if installation, recalibrations and repairs are carried out by personnel authorized by ALSA and if the unit is used in compliance with the given instructions in an area that meets all the applicable IEC or CEI requirements. The manufacturer is at disposal to supply, if requested, the electric diagrams and any further information.
**In accordance with the ALSA procedures for the after-sale control of the production, the users are pleased to inform the Manufacturer about every, even little, problem of this unit.**

## INTRODUCTION

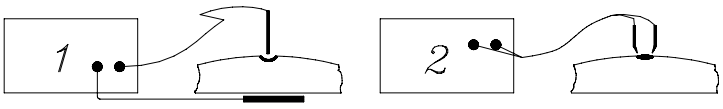
In a biological tissue crossed by an electric current are shown the following effects:
- thermal, faradic, electrolytic.

By using HF electric current the last 2 unisired and useless effects are eliminated and it is utilized above all the thermal effect. In fact when an electric current having such characteristics flows, from the active electrode to the neutral one, with sufficient density the cellular liquid of the tissues warms it and produces the following effects:

1) heating is so quick that the pressure of the vapour created in the cells breaks their membranes (cutting);
2) heating is lower, so the liquid slowly evaporates allowing the coagulation of the coagulable components of the tissues (coagulation or haemostasis);
3) the effect is a middle way between the two above-described ones (cut with coagulation).

The ESU is " HF device" that may destroy the cells of biological tissues and therefore it should be used by expert staffs in electrosurgery and respecting strictly all the given instructions.

The ALSATOM SU-MPC series can be used for every kind of monopolar/bipolar cut and coagulation/microcoagulation in:
**GYNAECOLOGY, DERMATOLOGY, PLASTIC SURGERY, DENTAL AND MAXILLO-FACIAL SURGERY, ANGIOLOGY, GENERAL SURGERY, ORL, GASTROENTEROLOGY, VETERINARY.**




In particular, the functions are as follows:

- **CUT:** Monopolar pure cut without coagulation
- **BLEND:** Monopolar cut with coagulation
- **COAG:** Monopolar coagulation (high voltage-fulguration)
- **COAG MICRO** Monopolar coagulation (low voltage-soft)
- **BIPOLAR** Bipolar coagulation.

**Before using these units, control their performance (for example on a piece of meat) without relying completely on the previous experiences with other devices. Always start with very low powers, then gradually raise up until obtain the desired surgical effect.**

## GENERAL PRECAUTIONS – It is dangerous to ignore the following warnings:

1- It is dangerous to use the device if the operating theatre doesnot meet CEI/IEC electrical requirements.
- Do not use "extension leads" for the power supply cable. Contact the technical department for the compatibility of other equipment eventually in use.

2- It is extremely dangerous to use accessories or instruments which are not perfectly compliant with all the applicable technical or legislative Rules, and which are not suitable for the working voltages of the device ( approx. 2800Vpp "1500Vp" for the monopolar currents with crest factors equal or higher than 2; 1200 Vpp "600Vp" for the monopolar currents with crest factors lower than 2; approx. 400Vpp "220Vp for the bipolar currents with crest factors equal or lower than 2). Moreover, the accessories and instruments must not be old nor worn. Check always their status before the use, notably if for endoscopy. Bear in mind that:
   - All the old/worn active electrodes, accessories and cables do not work properly, and do not guarantee the perfect insulation. In addition, their unstable functioning can lead the operator to increase the output powers at dangerous levels;
   - In the user manual, for each current, the maximum output voltage "Vpp" and its variation (see the curves) according to the output power adjustment are specified. This allows the operators to choose the maximum output power that must not be overcome, in order to not exceed the rated HF insulation voltage, which is possible for each accessory;
   - The standard monopolar active electrodes for normal surgery have a stem with Ø 2.3mm ( so, the standard electrode-holder handles are suitable for the electrodes having stems with this diameter).

3- The interference of HF units may harm the other electromedical equipments in use.

4- Contact cardiological department when using a HF unit on patient with pace-maker (the device can interfere its efficiency causing fibrillations and ect. or damage their electrodes).

5- Always take metal objects off the patients (ring, chain and etc.). Do not use a HF unit in the presence of flammable anaesthetic gases (i.e. oxygen, nitrogen protoxide and etc.) especially if operating in cavities (chest, abdomen, trachea, head, etc.)

6- Do not use flammable cleaning substances, disinfectants or solvents, or at least carefully evaporate them before operation. Always remove the remaining substances from hollow parts of the body or cavities (umbilicus, vagina, etc.) and from underneath. While using the device, a spark may cause the endogenous gas (intestine) explosion or set fire to oxygen saturated material (cotton, gauze, etc.).

7- Prevent the patient from touching any metal parts connected to earth or electricity conductors (table, supports, etc.) and isolate strongly secreting parts of the body and skin-to-skin contacts by using dry covers (i.e. between arm and body).

8- Position monitoring electrodes (not specifically shielded) as far as possible from the electrodes of the HF units. If possible avoiding the needle type or small-sized ones.

9- Use and position the neutral electrode as follows:
   - Choose an area of the body as near as possible to the area to be operated (the ideal is a flabby part without hairs where there are no protruding bones or uneven surfaces). Clean it, shave it and massage it to favour circulation.

- Firmly fix the electrode without placing anything in-between, ensuring the best contact possible over the entire surface but without pressing too hard to avoid creating ischemic areas (maybe use conductive gels, etc.) and always make sure that the contact is constant, especially if the patient is moved or when liquids are poured.

10- The position of the neutral electrode with regard to the operating area creates an HF current route and remember that any metal objects (prostheses, catherters, etc.) in that area may cause current concentrations that heat or even burn the adjacent tissue.

11- Position the cables of the electrodes so that they do not touch the patient or other wires.

12- Always use the lowest power possible to the surgical need.
The insufficient performance of the equipment may depend on: wrong positioning or faulty contact of the neutral plate, faulty connection of electrodes, poor conditions of the active electrode and therefore check these factors before increasing the power.

13- Use the bipolar technique for operating on small portions of tissues or in cavities.

14- When the unit is in use, don't touch with the active electrode the neutral one (short circuit) and try to avoid the activation when the active electrode doesn't touch the tissues – it might damage the unit or reduce its life. Please respect the suggested working times.

15- Contact the Technical Department for the use of "disposable" electrodes.

16- In case lack of supply mains, turn off the unit (setting output power at ZERO).

17- Pay attention that the fault of the HF unit might cause an unexpected power increase.

**POSITIONING OF THE PATIENT AND USING OF NEUTRAL PLATE**

By using monopolar technique, it is very important that all the currents reaching the patient must return to the unit via the neutral plate, otherwise two serious consequences will be encountered:

1. HF current discharges from the patient through an insufficient part of the same neutral plate or via casual contacts of conductive objects (operating table, wet clothes, supports and etc.), since these contact surfaces can be insufficient, the current crossing them may cause some burns.
2. Output power may lower considerably

Therefore **use and position the neutral plate respecting the par. "General Precautions".**

**Remember that, using a HF unit, it may occur phenomena generally named as "shocks" but these phenomena are normally only stimulations or radiofrequency discharges depending on the same contact between the operator and the patient. In case they happen it is advisable that the operator avoids the direct contacts with patient (e.g. use surgical gloves as insulating) and, if possible, has not ground contact (use clogs, insulating chair, and so on…).**

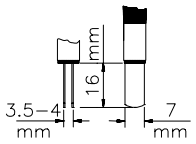
**SAFETY CIRCUIT OF THE NEUTRAL PLATE**

The unit is equipped with the neutral plate connection control circuit that, when the monopolar performance is selected, blocks the output power (if the neutral electrode is not connected or the relevant cable is broken) with specific alarm (intermittente sound and red light).
This circuit doesn't occur when the bipolar coagulation is selected but the red light signal is put on.

**WAY TO USE AND PRATICAL PROPOSALS**

1. Check the power supply mains (it must corres pond with the technical data at the back) and connect the device with main switch ( **1**) position OFF. Connect the pedal switch tubing (socket **3** at the back) crew tightly the connector **without pushing on the pedal (the mod. 140/D is provided with 2 sockets for the double pedal switch and the connection must be performed as follows:** yellow tubing of the double pedal to the left socket with yellow area, blue tubing of the double pedal to the right socket with blue area ). The pedal is pneumatic type, without electric current, waterproof and explosion proof.
2. Connect the electrodes as follows:
   - neutral electrode (socket **6**) and active electrode (socket **7**)
     **Modd. 140 and 140/D: hand-switch pencil (7A) pedal-switch pencil (7B). For endoscope cables and etc. use only socket 7B, if neccessary ask for specific adapters.**
   - Bipolar electrode (socket **8** without any polarity of the pins)

   The ALSA standard bipolar cable has this following connector:




3. Put on the unit by the switch **1**
4. Set up the initial power as follows:
   - modd. SU 100 and SU 50 by control **5**,
   - modd. SU 140 and SU 140/D by control **5A** (pure cut or blend cut), and control **5B** (coagulation, micro-coagulation, bipolar coagulation).
5. Select the performance by selector **4** and activate the output as follows:
   modd. SU 100 and SU 50 ..... (selector 4 - position: cut, blend, coag., micro coag., bip. coag.) **activation by single pedal switch;**
   mod. SU 140/D ..... (selector 4 – position: cut/ coag., cut/micro coag., blend/coag.,) **activation by hand switch pencil or double pedal switch (yellow for cut, blue for coagulation);**
   (selector 4 – position: bip. coag.) **activation by only the pedal switch (blue);**
   mod. SU 140 ..... (selector 4 – position: cut/coag.) **activation by hand switch pencil;**
   (selector 4 – position: cut, blend/coag., micro coag., bip. coag.) **activation by single pedal switch.**

   The activation is indicated: cut/blend by yellow light and low acoustic signal, coag./micro coag. by blue light and high acoustic signal, bipolar coag. by blue light and louder acoustic signal.

To optimize the running of the units follow the following general indications:

1. Do not activate the unit before touching the tissues by the active electrode (otherwise they will creat electric arcs able to produce eschar on tissue and preventing them from good cicatrization).
2. Keep the active electrode as clean as possible. The patina insulating on an electrode doesn't permit a good contact with the tissues, thus it lowers the output power and causes sparks or superficial carbonizations.

3. Using the pure cut (especially with the loop/conization electrodes) if the first effect is not satisfactory (with a slight sticking of the tissue on the electrode), to have the best result increase the power of 10÷15 W each time.

**Pure cut** **(for biopsy, laparoscopy, cut or skin incision, uterine conization in gynaecology etc., in general for any case needing cut without coagulating effect).**

1. Use small size electrodes, such as for ex.:
   - "thin needle electrode" (from 3÷4 W onwards)
   - SAD, SAD/1, SAD/2, SAD/3 "extra-fine needle electrodes" not insulated with diam. from 0.10 to 0.40 mm (from 3÷4 W onwards)
   - "fine loop electrodes" of different measures and shapes (from 8W onwards).
   - "long type electrodes" and "LLETZ type electrodes for gynaecology" (from 10W onwards)
2. Select "CUT" current

**Cut coagulating** **(for laparoscopy, polypectomies or papillotomies in endoscopy, fistulas, haemorrhoids and ect. In general for any case needing cut combined with an effective coagulating effect).**

1. Use the electrodes already mentioned for pure cut or, if possible, the ones with larger section, such as for ex.: knife and thick needle electrode (from 3÷4 W onwards)
2. Select "BLEND" current and slow a little the sliding of the electrode on the tissue. If coagulating effect is not enough, use even "COAG." current.

**Micro coagulation**

1. Use extra fine needles: AID "insulated needle" (the best for depilation), all the above mentioned "SAD" long type, not insulated needles for depilation, telangiectasia, spider naevi, pointformed red-ruby angiomas and ect.
2. Use ball electrodes to obtain deep effect avoiding as much as possible a surperficial sparking.
3. Select "COAG MICRO" current (from 0.5 Watt onwards)

**Coagulation**

1. Use ball electrodes, surgical forceps for coagulation with effective deep effect and good surperficial effect (fulguration).
2. Use small ball, needle, loop or for polipectomy electrodes, etc. to obtain strong superficial effect and limited deep effect.
3. Select "COAG" current (from 2-3 W onwards).

**Bipolar coagulation**

1. Use bipolar forceps or bipolar electrodes (also for laparoscopy or endoscopy, eventually supplied by the other manufacturers).
2. Select "BIP" current (from 2-3 Watt onwards)
3. Please remind that, to reduce the "sticking phenomena" of the tissue on the tips of the bipolar forceps during the operation, it is very useful to clam them as little as possible, reduce at maximum the time of activation and moisten them by physicological solution (or plunged inside a cup or on an imbibed gauze).

**AUTOTEST**

The running of the unit is completely controlled by microcontroller both during the working and when switching on (starting autotest which, if regular, ends with short acoustic signal). If any failure the system get blocked the output giving specific error codes (acoustic signals).

| TYPE OF FAILURE | NO. OF ACOUSTIC SIGNAL | SOLUTION |
|---|---|---|
| 1. memory RAM | 1 | Turn off and re-switch on the unit (if the problem continues, contact the technical assistance) |
| 2. CRC control software | 2 | " |
| 3. variables of the system | 3 | " |
| 4. supply voltage of microcontroller 4 | | " |
| 5. activation circuits | 5 | " |
| 6. output power higher than the selected value | 6 | " |
| 7. incorrect use of the selector 4 | 7 | Check the position of the selector |
| 8. got broken control 5 | 8 | As specified for Fault 1 |
| 9. continuous activation for more than 20s | 9 | Deactivate and reactivate immediately |
| 10. R.F. modulation signal | 10 | As specified for Fault 1 |
| 11. monitoring of the output current | 11 | " |
| 12. monitoring of R.F. supply | 12 | " |
| 13. watchdog timer | 13 | " |
| 14. intervention of neutral plate safety circuit | intermittent (grave) | Check the connection of the plug and the cable (bend and pull it, especially near the plug and the electrode). If the problem continues, contact the technical assistance) |
| 15. usage error (eg. Activation of cut function if selecting BIP or activation of 2 switches comtemporally) | Intermittent (acute) | Eliminate the cause |

Furthermore the following cases may occur:

1. the unit is ON (autotest OK), but when you press the pedal switch, it does not work (without acoustic or light signals) or works irregularly.
   a) check if the pedal is well connected;
   b) check if the pedal is broken by activating the unit pushing the central hole of the relevant socket with a round point. If the unit works regularly it is probably a problem of pedal.
2. the unit is ON (autotest OK), all the running is OK, but there is not output power or it is lower than the normal value.
   a) check the good contact of the neutral plate (if the contact is bad or absent there is no power). Remember that the hair of animals is insulating.

b) check if the active electrodes are damaged, if the contact with the pencil is good, if the pencil cable is broken (pull and bend it, especially near the plug and the handle).

If all the above mentioned interventions do not resolve, please contact the Technical Assitance.

## TECHNICAL FEATURES

- Electronic generator in compliance with the Safety Standards IEC 601-2-2 3^ed.
- Monopolar and Bipolar working frequency: 475 kHz
- Classification IEC: I type CF – Classification EC MDD: IIB
- Output circuit: "floating out" protected against the use of the defribrillator
- Mains and Absorption: *see rating on the back of the unit*
- Mains Fuses: *see rating on the back of the unit*
- Neutral plate safety circuit with acoustic signal (strong, intermittent) and luminous signal (red)
- Output power : setting by rotary switches
- Running control: by microcontroller with autotest, output error control, error codes
- Protection against liquids: common, not-protected casing
- Cooling by convection without ventilator
- Activation: discontinuous, 10s ON/30s OFF
- Dimensions and weight:
  cm (LxDxH) 23x24x10 – Kg 4.75 (modd. SU 140-MPC and SU 140/D-MPC)
  cm (LxDxH) 21x24x10 – Kg 4.50 (modd. SU 50-MPC and SU 100/D-MPC)

**Conformity EMC/Directive 89/336/CEE: Category A**
**Suggested distances to keep from not vital devices**

| Source of the Current RF | Typical Power (W) | Distance (m) |
|---|---|---|
| Microcellular telephones CT1,CT2,CT3 | 0.01 | 0.4 |
| Mobile telephones DECT, Wireless devices (modems, LANs) | 0.25 | 2 |
| Mobile telephones (USA) | 0.6 3 | |
| Hand mobile telephones (GSM, NMT, Europe)<br>(DECS 1800) | 2<br>8 | 6<br>11 |
| Walkie-talkie (police, firemen , protection, maintenance) | 5 | 9 |
| Bag mobile telephones | 16 16 | |
| Mobile radio (police, firemen, protection) | 100 | 40 |

For broadcasting stations which use frequencies less than 800MHz, the distance can be established by using the equation: A: $d = 4\sqrt{P}$
For broadcasting stations which use frequencies between 800MHz and 2.5GHz, the distance can be established by using the equation:
B : $d = 2.3\sqrt{P}$
P = Nominal power of the transmitter in watt (W), established by the manufacturer.

### Output power, Vpp-open circuit, Crest factors (SU 100-MPC, SU 140-MPC, SU 140/D-MPC)

| | | |
|---|---|---|
| Cut: | 140 WRMS | at 500 Ohm (Vpp 1200, cf 1.7) |
| Blend: | 120 WRMS | at 500 Ohm (Vpp 1450, cf 2.8) |
| Coag: | 120 WRMS | at 500 Ohm (Vpp 1952, cf 6.9) |
| Coag Micro: | 60 WRMS | at 200 Ohm (Vpp 1420, cf 2.8) |
| Bipolar: | 100 WRMS | at 100 Ohm (Vpp 400, cf 1.4) |

### Output power, Vpp-open circuit, Crest factors (SU 50-MPC)

| | | |
|---|---|---|
| Cut: | 80 WRMS | at 500 Ohm (Vpp 1000, cf 1.7) |
| Blend: | 80 WRMS | at 500 Ohm (Vpp 1420, cf 2.8) |
| Coag: | 80 WRMS | at 500 Ohm (Vpp 1950, cf 6.9) |
| Coag Micro: | 60 WRMS | at 200 Ohm (Vpp 1420, cf 2.8) |
| Bipolar: | 60 WRMS | at 100 Ohm (Vpp 400, cf 1.4) |

## ATMOSPHERIC CONDITIONS

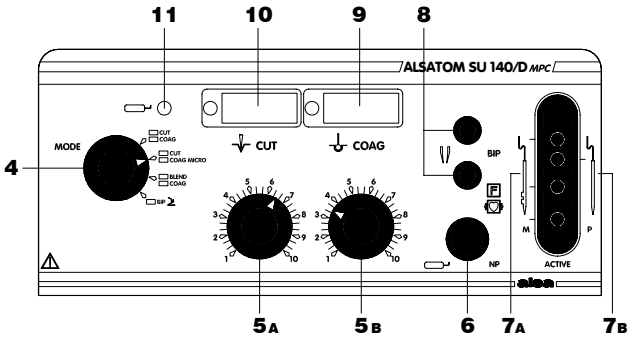
| **usage** | | **transport and storage** | |
|---|---|---|---|
| Temperature (°C) | +10 ÷ +40 | Temperature (°C) | -40 ÷ +70 |
| Humidity | 30% ÷ 75% | Humidity | 10% ÷ 95% |
| Pressure (hPA) | 700 ÷ 1060 | Pressure (hPA) | 500 ÷ 1060 |

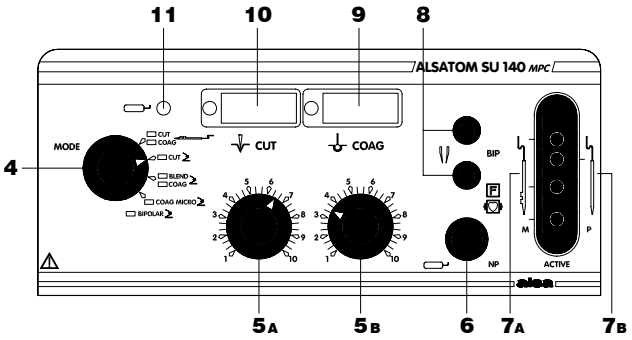
## CLEANING, STERILIZATION, MAINTENANCE, DISPOSAL

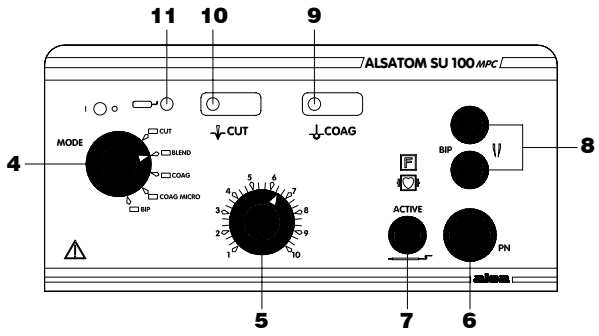
1. Clean the unit by neutral soap solution (**pay attention: any liquid doesn't go inside**) and wipe it, keep in a dry and not-dusty place and ensure that is not poured any liquid on it.
2. The unit must be periodically checked (at least once per year) by qualified staff, better by the Manufacturer. Always control the accessories, if they are not in p erfect condition they can be d angerous (eg. Bro ken cables, dirty electrodes, pins clamped b y jury means and etc.)
3. Waste of the unit must respect every specific national rules.
4. **Attention, at the moment of the sale the accessories are not sterile. All the monopolar and bipolar accessories are sterilizable by autoclave (121°C) or by cold solution (ex. Cydex), the neutral plates by cold solutions only. Sterilize them as indicated in the instruction of every single package.**

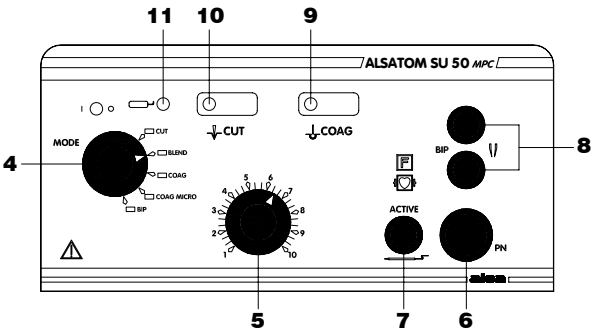
## STANDARD ACCESSORIES

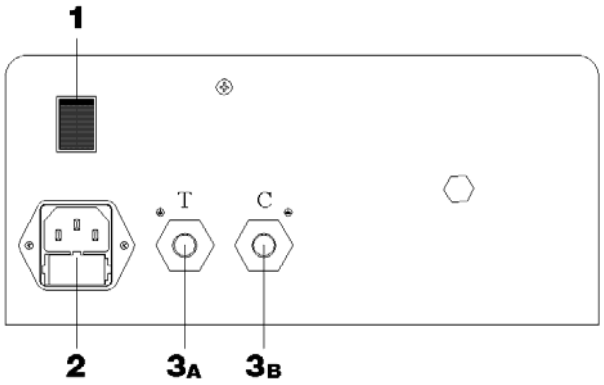
| | |
|---|---|
| MPE/E | - Sterilizable pencil with connection cable.(Rated voltage = 4000 Vp) |
| SEL/VI | - Set of 6 electrodes. (Rated voltage = 4000 Vp) |
| EIP/9 | - Neutral plate with connection cable. |
| FFE | - Fixing rubber belt for neutral electrode. |
| D-STOP/P | - Double pneumatic pedal switch (mod. SU 140/D-MPC) |
| STOP/PN | - Pneumatic pedal switch (modd. SU 50-MPC, SU 100-MPC, SU 140-MPC). |




**At the back**

1- Main switch ……. symbol: (switching on) itching off)

2- Power entry module with double fuse-holder

3- Connection pedal switch ……symbol

only 140/D model:

A = cut (yellow signal)

B = coagulation (blue signal)

**In the front**

4 Function selector

5 Output power setting (modd. 140 and 140/D:A = pure cut and blend cut; B= coagulation, micro coagulation, bipolar coagulation)

6 Neutral plate socket ..... symbol:

7 Active electrode socket (modd. 140 and 140/D: A= hand switch handle..... symbol:

( " " B= pedal switch handle..... symbol:

(modd. 100 and 50 .....symbol:

8 Bipolar electrode socket .....symbol:

9 Output activation/coagulation: (blue light) with display (only modd. 140 and 140/D)..... symbol:

10 Output activation/cut: (yellow light) with display (only modd. 140 and 140/D)..... symbol:

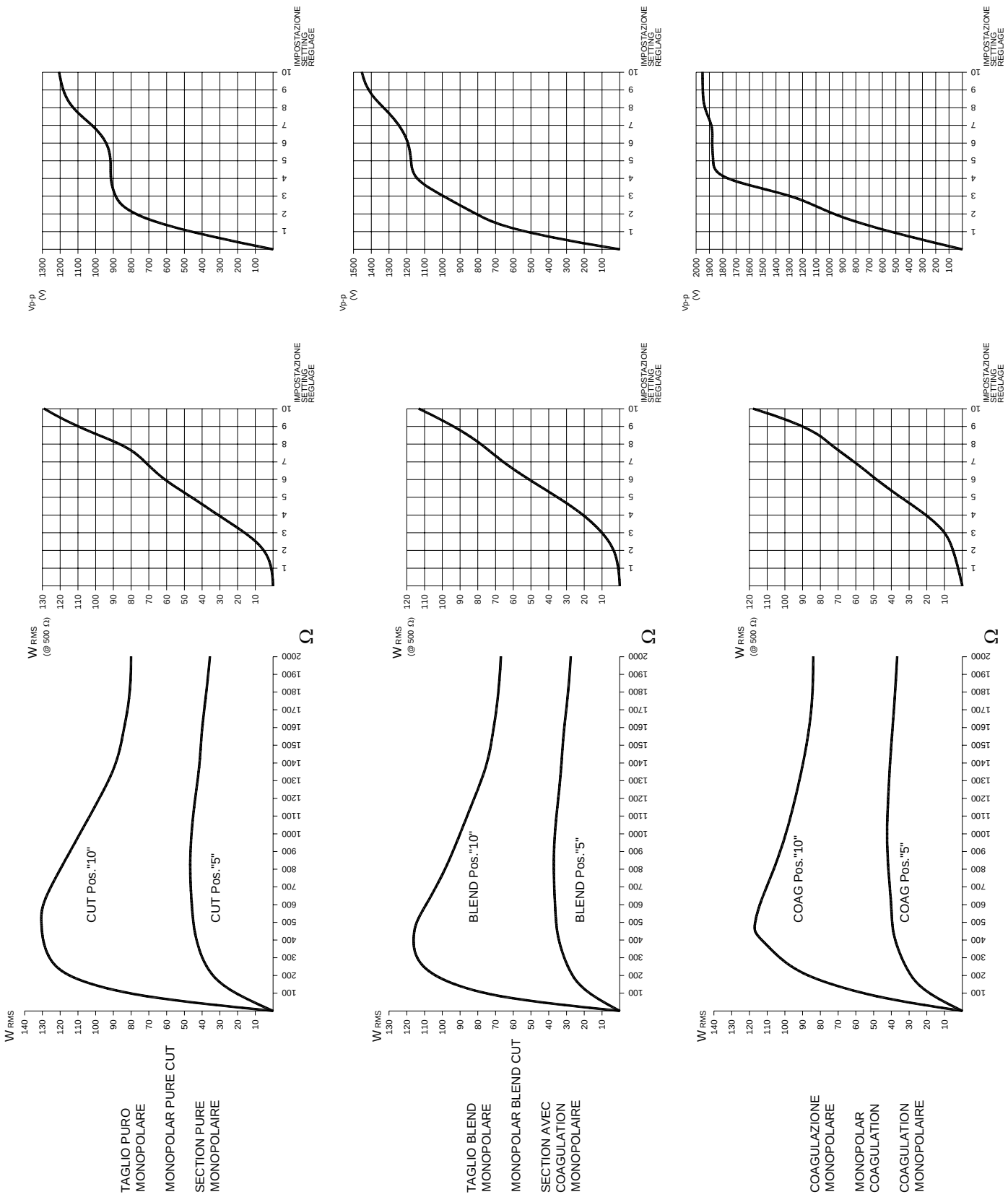
11 Neutral plate safety circuit (red light) ..... symbol:

Be careful: read the annexed documentation: ..... symbol:

Apparatus of Class I - Type CF – protected against the effect of the defibrillator ... symbol:

Alternating current .....symbol:

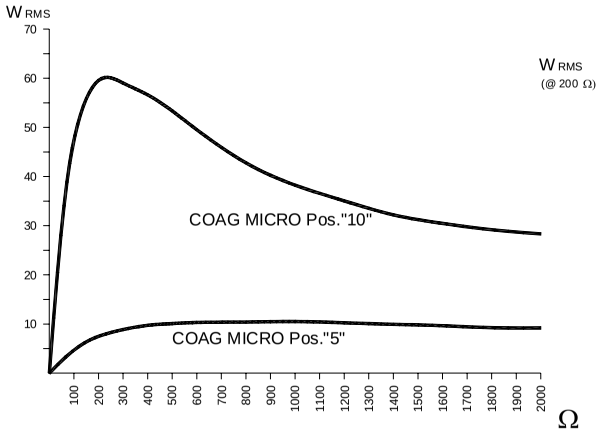
**POWER OUTPUT DIAGRAMS (± 20% ) – Modd. SU 100-MPC, 140-MPC, 140/D-MPC (NOTE: in model SU 140-MPC, BLEND diagram corresponds to BLEND/COAG position of the mode selector)**

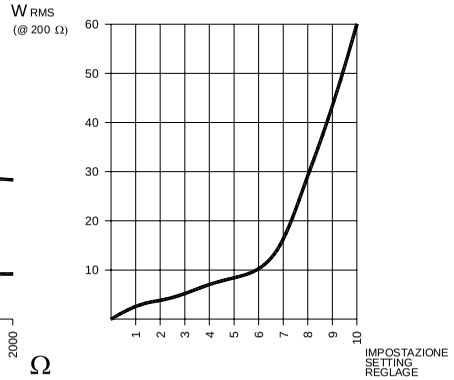


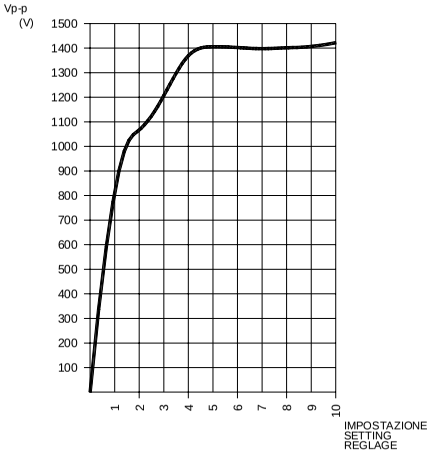
COAGULAZIONE MICRO MONOPOLARE

MONOPOLAR MICRO COAGULATION

MICRO COAGULATION MONOPOLAIRE



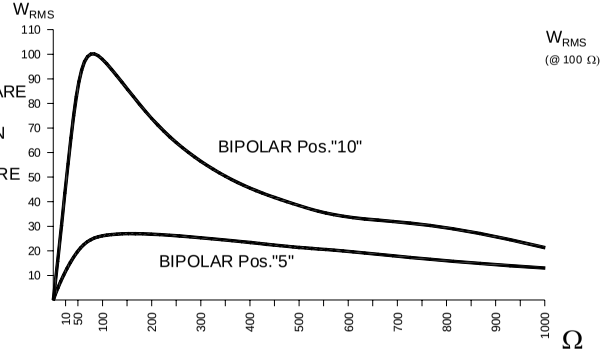



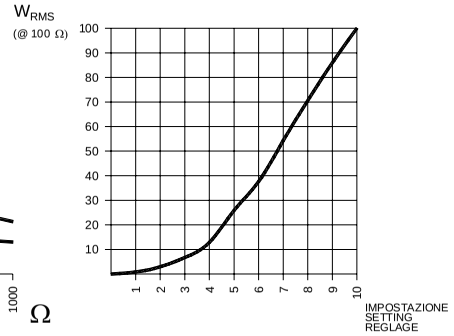



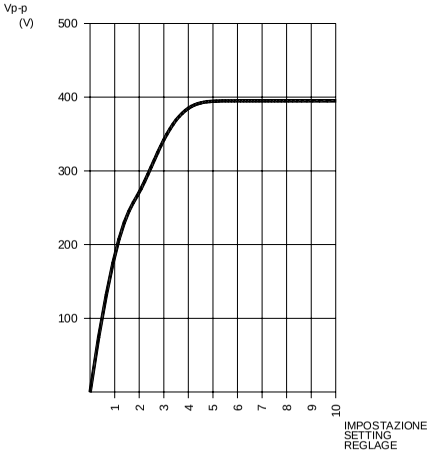

COAGULAZIONE BIPOLARE

BIPOLAR COAGULATION

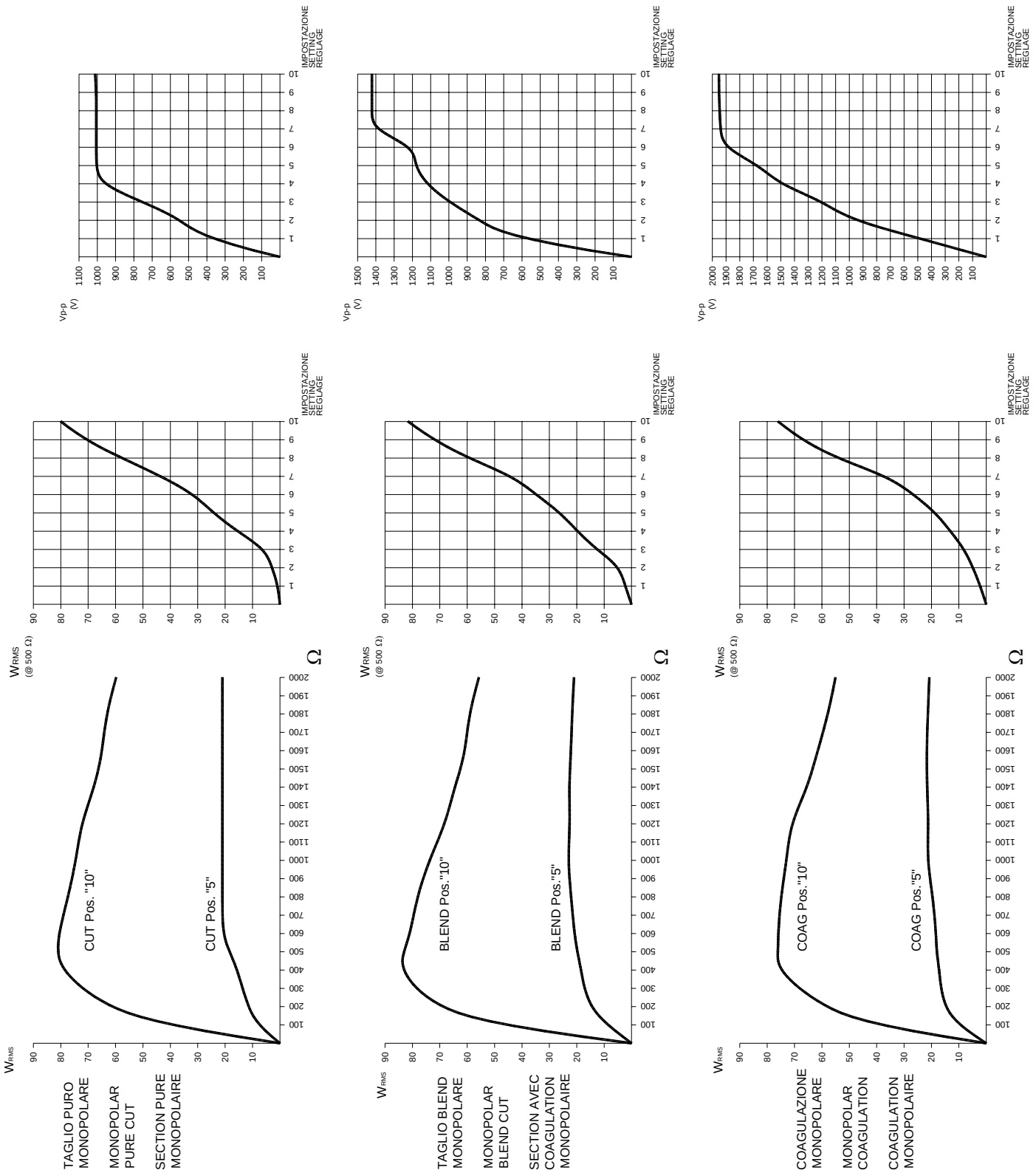
COAGULATION BIPOLAIRE

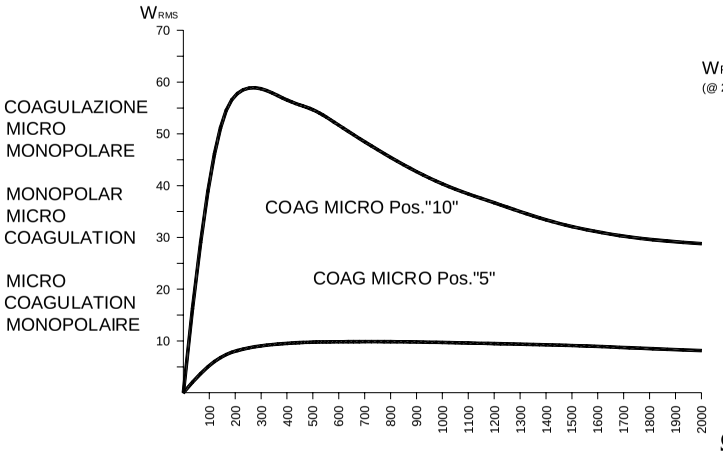


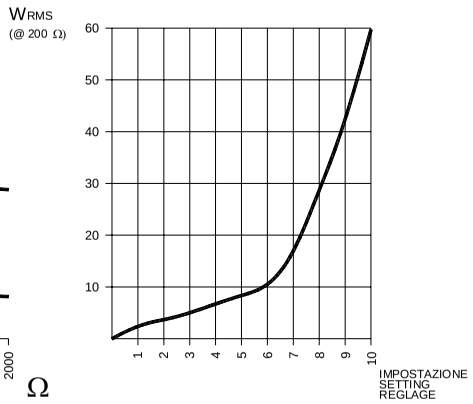



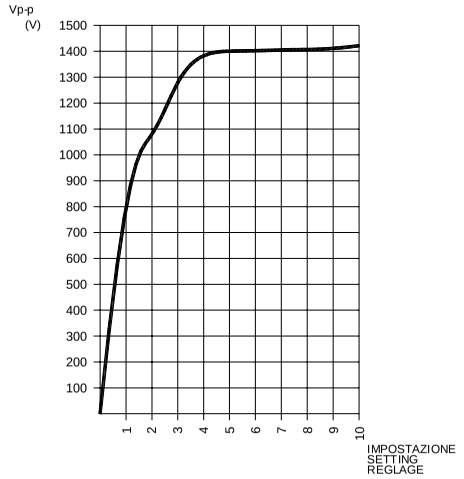



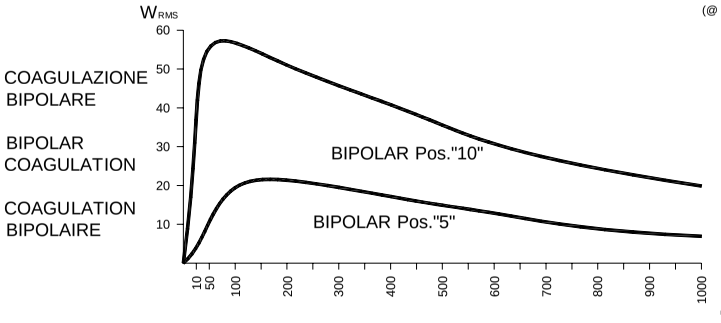
**POWER OUTPUT DIAGRAMS (± 20% ) – SU 50-MPC**

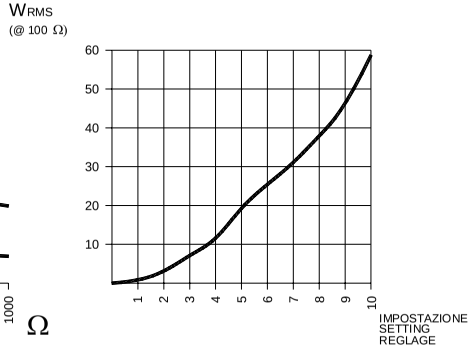


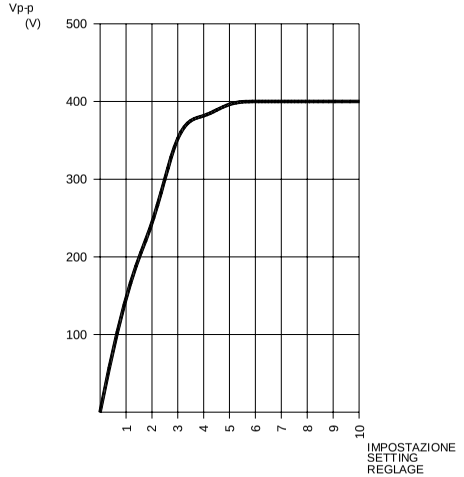

W RMS
70
60
50
40
30
20
10
COAGULAZIONE
MICRO
MONOPOLARE
MONOPOLAR
MICRO
COAGULATION
MICRO
COAGULATION
MONOPOLAIRE
COAG MICRO Pos."10"
COAG MICRO Pos."5"
100 200 300 400 500 600 700 800 900 1000 1100 1200 1300 1400 1500 1600 1700 1800 1900 2000
Ω


W RMS
(@ 200 Ω)
60
50
40
30
20
10
1 2 3 4 5 6 7 8 9 10
IMPOSTAZIONE
SETTING
REGLAGE


Vp-p
(V)
1500
1400
1300
1200
1100
1000
900
800
700
600
500
400
300
200
100
1 2 3 4 5 6 7 8 9 10
IMPOSTAZIONE
SETTING
REGLAGE


W RMS
60
50
40
30
20
10
COAGULAZIONE
BIPOLARE
BIPOLAR
COAGULATION
COAGULATION
BIPOLAIRE
BIPOLAR Pos."10"
BIPOLAR Pos."5"
10 50 100 200 300 400 500 600 700 800 900 1000
Ω


W RMS
(@ 100 Ω)
60
50
40
30
20
10
1 2 3 4 5 6 7 8 9 10
IMPOSTAZIONE
SETTING
REGLAGE


Vp-p
(V)
500
400
300
200
100
1 2 3 4 5 6 7 8 9 10
IMPOSTAZIONE
SETTING
REGLAGE